

II. REMARKS

Introductory Comments

Claims 1-25 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. § 101 for double patenting; and (2) over the judicially created doctrine of obviousness-type double patenting. These grounds of rejection are believed to be overcome by this response and are otherwise traversed for reasons discussed in detail below.

Overview of the Above Amendments

Claims 1, 5, 7, 9, 13 and 15 have been amended to recite the invention with greater particularity. Specifically, claims 1 and 9 have been amended to recite that the nucleic acid molecule comprises “in 5’ to 3’ order” an AAV *rep* coding region, an AAV *cap* coding region, and the modified AAV p5 promoter region. Support for this recitation can be found in example 1 where the construction of plasmid pHLP19 is detailed, and in Figure 4 that shows the orientation of *rep*, *cap* and the p5 promoter region. Further support can be found at page 19, line 20. Additionally, claims 5 and 13 have been amended to depend from claims 3 and 11, respectively. Claims 7 and 15 have also been amended to depend from claims 3 and 11, respectively and to conform the language to these claims.

Claims 4, 6, 12, 14 and 17-25 have been cancelled. Cancellation of these claims and amendment of claims 1, 5, 7, 9, 13 and 15 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications containing the unamended claims.

The Double Patenting Rejections:

Claims 1-25 were rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 2, 4-6, 8, 3, 7, 9, 10, 24, 15, 16, 20, 11, 17, 12, 18, 21-23, 25, 19, 24 and 13, respectively, of U.S. Patent No. 6,001,650. However the independent claims in the present application have both been amended to recite that the components of the nucleic acid molecule occur in “5’ to 3’ order.” This limitation is not present in the claims of the ‘650 patent. Thus, the

present claims are of different scope than the claims of the '650 patent and the rejection for double patenting under 35 U.S.C. §101 should be withdrawn.

Claims 1-25 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,376,237. Applicant respectfully traverses this rejection. The claims of the '237 patent are all directed to stocks of rAAVs that are free of wild-type or psuedo-wild-type AAV, wherein the rAAV comprises a packaged rAAV vector containing a heterologous gene of interest but lacking AAV genes required for replication or packaging of the AAV vector. There are no claims directed to methods of making the stock, nor are there any recitations in the claims of the '237 patent concerning a nucleic acid molecule encoding AAV helper functions or of an AAV helper function vector. Accordingly, the obviousness-type double patenting rejection over the '237 patent is believed to be in error and this basis for rejection should be withdrawn.

Claims 1-25 were also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 8 and 12-15 of U.S. Patent No. 6,365,403. Applicant requests this rejection be held in abeyance until allowable subject matter is indicated. Applicant will then assess the propriety of filing a Terminal Disclaimer.


Finally, the Office rejected claims 26-41 under the judicially created doctrine of obviousness-type double patenting over claims 1, 6, 10 and 11 of U.S. Patent No. 6,027,931. However, claims 26-41 are not pending in this application. Accordingly, withdrawal of this basis for rejection is respectfully requested.

III. CONCLUSION

In view of the foregoing, applicant submits that the claims are now in condition for allowance and request early notification to that effect. If the Examiner notes any further matters which she believes may be resolved by a telephone interview, she is encouraged to contact Christina Thomson by telephone at (510)748-7208, or by fax at (510)748-7368.

Respectfully submitted,

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By: 
Roberta L. Robins
Registration No. 33,208

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Telephone: (650) 493-3400
Facsimile: (650) 493-3440